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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	37697-0033	8881
26633	7590	05/28/2004	[REDACTED]	EXAMINER
HELLER EHRMAN WHITE & MCAULIFFE LLP				TRUONG, DUC
1666 K STREET, NW				
SUITE 300			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20006			1711	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/764,445	MERRILL ET AL.	
<b>Period for Reply</b>	<b>Examiner</b>	<b>Art Unit</b>	
	Duc Truong	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 124-143 is/are pending in the application.

    4a) Of the above claim(s) 131-142 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 124-130 and 143 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) All b) Some \* c) None of:

        1. Certified copies of the priority documents have been received.

        2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.

        3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0524

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant argues that the earliest effective filing date is February 13, 1996 from US Serial No 08/600,744 and 08/726,313. Further, a Declaration filed under 37 CFR & 1.608 has been submitted to support for Applicant's arguments.

Note that in the comparative examples between the instant claims and the '744 reference, Applicant argues that packaging step is a known requirement of medical implants to protect them from the environment. See Exhibit 2.; and the sterilizing the packaged implant using non-irradiative methods is a known requirement for medical implants. However, they must be support from the specification to show that this step must be used in the process, otherwise, a new issue or new matter can be raised.

Claim 128 discloses : "a crosslinked ultrahigh Mw polyethylene having a swell ratio of less than about 5 and an oxidation level of less than about 0.2 carbonyl area/mil sample thickness after aging the ultrahigh Mw polyethylene at 70 C, for 14 days in oxygen at a pressure of about 5 atmospheres". These characteristics could not located anywhere in the Specification. The Declaration has been fully considered but they are not persuasive since they do not have support from the specification.

Therefore, the earliest filing date of this application is February 11, 1997.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless ~

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 124-130 and 143 are rejected under 35 U.S.C. 102(a) as being anticipated by Saum et al'975.

The reference discloses a process for preparing a medical implant having an improved balance of wear properties and oxidation resistance.

The reference further discloses a medical implant of ultrahigh molecular weight polyethylene having an improved balance of wear properties and oxidation resistance prepared by irradiating a preform of ultrahigh MW polyethylene, annealing the irradiated preform in the absence of oxygen to a temperature at or above the onset of melting temperature, and forming the implant from the stabilized crosslinked polymer (see Abstract and at col. 2, lines 46 et seq.).

Note that claim 124 of this application is identical with claim 1 of the reference and at col. 2, lines 48 et seq.

Note also that claim 124 is identical with claim 15 of the reference.

Note also that claim 128 is identical with claim 32 of the reference and at col. 3, lines 1 et seq.

Note also that claim 130 is identical with claim 35 of the reference.

Note also that claim 143 is read on the teaching of the reference at col. 2, lines 50 et seq.

Thus, each and every limitation of the claims is met by the reference.

Claims 124 and 130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for forming the medical implants, does not reasonably provide enablement for the steps of packaging and sterilizing the packaged

implant using non-irradiative methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The packaging and the sterilizing the packaged implant step are not located anywhere in the specification.

Claim 128 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crosslinked ultrahigh molecular weight polyethylene, does not reasonably provide enablement for having a swell ratio of less than about 5 and an oxidation level of less than about 0.2 carbonyl area/mil sample thickness after aging the ultrahigh molecular weight at 70 C, for 14 days in oxygen at a pressure of about 5 atmospheres. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. These characteristics are not located anywhere in the specification, even at Table 1-4, as suggested by Applicant. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Duc Truong whose telephone number is 571-272-1081. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9791 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1711

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



DUCTRUONG  
PRIMARY EXAMINER

DT  
May 24, 2004